IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

IN RE: AFLIBERCEPT PATENT LITIGATION **MDL No. 1:24-MD-3103**

This Document Relates to:
No. 1:22-CV-61

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ORDER GRANTING MOTION FOR PERMANENT INJUNCTION

Pending before the Court is Plaintiff's Motion for Permanent Injunction [ECF No. 708[1]]. The motion is fully briefed and, therefore, ripe for decision. For the reasons stated herein, the motion is **GRANTED**.

I. BACKGROUND INFORMATION

A. Regeneron and Its Eylea Products

Regeneron invented and developed Eylea, which the U.S. Food and Drug Administration ("FDA") approved on November 18, 2011. The Court has previously addressed the pertinent background and development of Eylea. See Regeneron Pharms., Inc. v. Mylan Pharms. Inc., --- F. Supp. 3d ---, 2024 WL 382495, at *13-14 (N.D.W. Va. Jan. 31, 2024) (discussing relevant background of Eylea). "Eylea is an ophthalmic drug product invented by Regeneron scientists that has been used to treat millions of patients suffering from

[1] Unless noted otherwise, the docket numbers cited in this Order refer to the docket in Case No. 1:22-CV-61.

diseases that can cause vision loss or even blindness." Id. at *13. The active ingredient in Eylea is the fusion protein now referred to as aflibercept. Aflibercept was initially developed as a cancer therapeutic, and Regeneron later discovered that aflibercept could be used to treat angiogenic eye diseases — eye diseases caused by uncontrolled blood vessel growth in the retina — through intravitreal injections (injection into the vitreous of the eye). Id. at *13-14.

Only after more than a decade of development and multiple clinical trials did Regeneron discover an Eylea formulation that improved on the leading treatment for one angiogenic disease— wet Age-Related Macular Degeneration ("AMD"). Id. at 13 (quoting Trial Tr. 172:16-24 (Yancopoulos) (ECF No. 558)). The Eylea formulation contains 40 mg/mL aflibercept, 10 mM sodium phosphate, 40 mM sodium chloride, 0.03% polysorbate 20, and 5% sucrose, pH 6.2. Id. Following its initial FDA approval, Regeneron tested Eylea's safety and efficacy in patients with other angiogenic eye disorders, ultimately obtaining approval for Eylea's use to treat those conditions as well. Id.

Following the success of Regeneron's Eylea vial formulation, Regeneron developed two other Eylea products containing aflibercept, which also treat angiogenic eye disorders. In August

2019, FDA approved Eylea as a 2 mg single-dose injection packaged in a prefilled syringe ("PFS"). A pre-filled syringe is "ready to inject," once a provider opens the package. Clark Tr. 38:13-19. In contrast, "when a product is in a vial, a physician or their staff needs to take it out of the refrigerator, potentially warm it for a little bit, draw it up," which can take more time. See id. Regeneron's Eylea PFS product is approved to treat the same conditions as the vial product. Clark Decl. ¶ 3 (ECF No. 708-16). In August 2023, Regeneron received approval to sell Eylea HD, an 8 mg formulation that requires less frequent injections and provides improved anatomical outcomes in the form of drier retinas. Sheridan Decl. ¶ 48 (ECF No. 708-4); Clark Decl. ¶ 3. Eylea HD is currently approved to treat wet AMD, Diabetic Retinopathy ("DR"), and Diabetic Macular Edema ("DME"). Clark Decl. ¶ 3.

B. Other Anti-VEGF Treatments

For the past five years, Eylea has maintained its place as the "category leader" in anti-VEGF treatments, [redacted] The second most popular anti-VEGF agent, Avastin (bevacizumab), [redacted] Avastin is an oncology drug for metastatic colorectal cancer (among other cancers), but

ophthalmologists sometimes use it off-label (i.e., for diseases for which it does not have FDA approval) to treat angiogenic eye disorders. Sheridan Decl. ¶ 55. The third- and fourth-most popular anti-VEGF agents, Vabysmo (faricimab) and Lucentis (ranibizumab), are approved to treat angiogenic eye disorders. Id. ¶¶ 57-59. Genentech manufactures all three drugs. Id. ¶¶ 55, 57-59.

Eylea, Avastin, Vabysmo, and Lucentis make up more than 96% of anti-VEGF ophthalmic sales. Clark Decl. ¶ 6; Clark Ex. 1 at -399. Other products on the market, such as Beovu, are prescribed less frequently. Trial Tr. 861:6-862:4 (Albini) (ECF No. 571). According to Regeneron, Eylea has maintained its category leadership due to its safety, efficacy, and dosing advantage. Clark Decl. ¶ 7; see infra pp. 13-14.

C. Aflibercept Biosimilars

At least [redacted] pharmaceutical companies are developing and seeking FDA approval for aflibercept biosimilars, each of which contains the same active ingredient as Eylea, also in a 2 mg vial formulation. Sheridan Decl. ¶ 49. Absent injunctive relief, Regeneron expects [redacted] Defendants' aflibercept biosimilar, Yesafili, is among

the closest to launch, having received FDA approval on May 20, 2024. See infra.

II. PROCEDURAL HISTORY

Mylan informed Regeneron on January 2, 2022 that it had applied for FDA approval of M170, "a proposed biosimilar to aflibercept," which Regeneron markets under the brand name Eylea. ECF No. 692 at 5; 42 U.S.C. § 262(l)(2). Regeneron responded by providing the list of patents it would consider asserting against Mylan. ECF No. 692 at 5; 42 U.S.C. § 262(l)(3)(A). The parties then went through the "patent dance," a series of information exchanges laid out in 42 U.S.C. § 262(l) designed to address patent disputes about proposed biosimilars.

Regeneron filed a complaint against Mylan on August 2, 2022, asserting that M710, which would be marketed as Yesafili, would infringe at least twenty-four of Regeneron's patents. ECF No. 1; see also 42 U.S.C. § 262(l)(6)(B) (authorizing an immediate patent infringement action if the parties cannot reach an agreement). Mylan later transferred its rights in Yesafili to Biocon, a biopharmaceutical company based in India, and the parties agreed to join Biocon as a Defendant-Counterclaim Plaintiff in this action. ECF No. 523 at 1-2; Trial Tr. 310:7-15 (Csaky) (ECF No. 559).

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Regeneron sought an expedited trial schedule, which the Court granted over Defendants' objection, to seek permanent injunctive relief before the FDA approved Yesafili. ECF No. 7 at 5. The Court issued a Scheduling Order allowing for an initial trial on a narrowed set of patents and claims in June 2023. ECF No. 87 at 1-2. Shortly after the Order, Regeneron identified six patents from three patent families for claim construction and trial: U.S. Patent Nos. 10,888,601; 11,053,280; 11,084,865; 11,104,715; 11,253,572; and 11,299,532. ECF No. 88 at 1.

The parties cross-moved for summary judgment before trial. ECF Nos. 428, 429. Mylan moved for summary judgment as to certain claims directed to treatment regimens. In its April 2023 claim construction ruling, the Court found certain language in these claims to be non-limiting and lacking patentable weight. ECF No. 427 at 37-39. As a result, Regeneron stipulated to the invalidity of claims 5, 6, and 9 of the '601 Patent and claims 1-5, 8-11, 14, and 26-28 of the '572 Patent, while preserving its appellate rights, and narrowed the patents and claims for the initial trial.[2]

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[2] In its stipulation, Regeneron also accepted summary judgment of noninfringement of certain claims of U.S. Patent No. 11,104,715 based on the Court's claim construction ruling, subject to Regeneron's appellate rights. ECF No. 433. The '715 Patent was not at issue in the parties' June 2023 trial.

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ECF No. 433 at 1. The Court denied the remainder of the parties' summary judgment motions. ECF No. 525.

The next month, Regeneron further narrowed the patents and claims for the initial trial to the following claims from three patents: in U.S. Patent No. 10,888,601, claims 11 and 19; in U.S. Patent No. 11,084,865, claims 4, 7, 9, 11, 14-17; and in U.S. Patent No. 11,253,572, claims 6 and 25 (the "Initial Claims").

The Court held a two-week bench trial on the Initial Claims in June 2023, hearing testimony from several fact and expert witnesses. After the trial, the parties filed three rounds of post-trial briefing, and the Court heard closing arguments on August 3, 2023.

On January 31, 2024, the Court issued a detailed Memorandum Opinion and Order holding that Regeneron demonstrated by a preponderance of the evidence that Defendants' Yesafili product infringed claims 4, 7, 9, 11, and 14-17 of the '865 Patent (the "Product Patent") and that Defendants failed to establish those claims are anticipated, obvious, or invalid. ECF No. 692 at 311-12. The Court also held that Defendants' marketing of their Yesafili product would induce infringement of claims 6 and 25 of the '572 Patent and claims 11 and 19 of the '601 Patent, but it concluded that Mylan demonstrated by clear and convincing evidence

that these claims are invalid as obvious (but not anticipated). Id. at 312-13. In sum, the Court found that Yesafili infringed eight claims in Regeneron's Product Patent, which are valid and do not expire until June 14, 2027.

Following this Court's ruling, Regeneron petitioned the Judicial Panel on Multidistrict Litigation to coordinate this action with five other patent infringement lawsuits relating to aflibercept biosimilar launches, which Regeneron filed in this district and the Central District of California. See 28 U.S.C. § 1407. On April 11, 2024, the Panel granted Regeneron's motion and consolidated the cases into In re: Aflibercept Patent Litigation, centralizing them in this district. Transfer Order, In re: Aflibercept Patent Litig., MDL No. 1:24-md-3103-TSK (Apr. 11, 2024), ECF No. 1 ("MDL ECF No."). Regeneron's claims against Amgen, Inc., Celltrion, Inc., Formycon AG, and Samsung Bioepis Co., Ltd., are thus also pending before this Court.

On February 22, 2024, Regeneron moved for a permanent injunction to prohibit Mylan and Biocon from launching Yesafili before the Product Patent expires, citing Defendants' continued efforts to market Yesafili [redacted]. Regeneron PI Br. at 1 (ECF No. 708-3). Again, the motion is fully briefed and ripe

for the Court's decision. Id.; Opp. (ECF No. 722-1); Reply (ECF No. 747-2).

Seeking to prevent Defendants from launching Yesafili while the Court considered the permanent injunction motion, Regeneron moved for a temporary restraining order, which Defendants opposed. ECF Nos. 70, 105. On May 17, 2024, the Court granted Regeneron's motion after finding that "Regeneron has clearly shown through specific facts in an affidavit that any manufacture, importation, or commercialization of YESAFILI prior to the expiry of the '865 Patent will cause it immediate and irreparable injury, including to Regeneron's market share, pricing, goodwill with patients and clinicians, and/or research and development funding as a result of facing improper competition from an infringing product." ECF No. 776 at 2-3. The Court determined that "[s]uch injury would not be fully redressable by monetary damages." Id. at 2. It then "enjoined and restrained" Defendants "from manufacturing, using, offering to sell, or selling within the United States, or importing into the United States without a license from Regeneron . . . YESAFILI" for "fourteen days," unless extended for "good cause." Id. On May 20, 2024, the FDA approved Yesafili as an interchangeable biosimilar to Eylea. The FDA approved Yesafili as a treatment for wet AMD, DR, DME, and Macular Edema

following Retinal Vein Occlusion ("RVO"). See *FDA Approves First Interchangeable Biosimilars to Eylea to Treat Macular Degeneration and Other Eye Conditions*, U.S. Food & Drug Admin. (May 20, 2024), https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye.

III. FACTUAL BACKGROUND

A. Permanent Injunction Expert, Fact Declarants and Irreparable Harm Declarants

Regeneron supported its motion for a permanent injunction with a declaration from one fact witness and one expert witness. Defendants provided one fact witness declaration and two expert witness declarations. All declarants were deposed, and the parties relied on this deposition testimony in their briefing.

1. Kevin Clark

Kevin Clark is Vice President of Regeneron's Ophthalmology Commercial Business Unit, a role he has held since 2020. Clark Decl. ¶ 1. Mr. Clark's focus at Regeneron has been on the commercialization of Eylea and Eylea HD. Id. ¶ 3. Mr. Clark's declaration addressed the effect of biosimilar entry on Regeneron and its Eylea product from Regeneron's perspective.

2. Matthew Erick

Matthew Erick is Chief Commercial Officer of Biocon's Advanced Markets unit, where he directs the commercial strategy for Biocon's biosimilar business in the United States, among other areas. Erick Decl. ¶¶ 1-2 (ECF No. 722-16). Prior to joining Biocon, he worked for Mylan for nearly ten years, including as President of the Sales & Marketing unit for North America. Id. ¶ 6. [redacted]

3. Dr. Sean Sheridan

Dr. Sean Sheridan is a Vice President at Charles River Associates, an international business consulting firm, and has a Ph.D. in genetics as well as an M.B.A. with concentrations in finance and economics from the University of Chicago. Sheridan Decl. ¶¶ 1-2. Dr. Sheridan's declaration addressed whether

Regeneron would be irreparably harmed by market entry of Eylea biosimilars prior to expiry of the asserted patents. Dr. Sheridan's previous experience has included the quantification of economic damages, and he has experience in modeling and valuation in a variety of intellectual property matters. Id. ¶¶ 3-5.

4. Dr. Ivo Abraham

Dr. Ivo Abraham is a Professor of Pharmacy, Professor of Medicine, and Professor of Clinical Translational Sciences at the University of Arizona. Abraham Decl. ¶ 1 (ECF No. 722-17). He is also Co-Founding Principal and Chief Scientist at Matrix45 LLC, a research and consulting group that advises pharmaceutical companies and other stakeholders on development and post-approval marketing of pharmaceuticals. Id. ¶ 5. Dr. Abraham, trained as a registered nurse, describes himself as "an advocate for biosimilars" and has studied the cost-efficiency of expanded access to biosimilars. Abraham Tr. 52:5-10; see Abraham Decl. ¶ 5. Dr. Abraham's declaration addresses how biosimilars' entry into the market can promote cost-savings and "create alternative sources of important therapies." Abraham Decl. ¶¶ 15, 18.

5. Christopher Spadea

Christopher Spadea is the principal owner of Folio Expert Services, LLC, which provides expert testimony, valuation,

licensing, and other consulting services to clients in the pharmaceutical and other industries. Spadea Decl. ¶ 2 (ECF No. 722-18). He has no specialized knowledge regarding the ophthalmology pharmaceutical industry, however, and was unclear about what anti-VEGF drugs that were cited in his report were actually used for ophthalmic applications. Id. ¶ 13; Spadea Tr. 120:5-124:12 (stating that he obtained that information from drugs.com and that he did not know whether Sprycel was used for ophthalmic purposes or available as an intravitreal injection). In his declaration, Mr. Spadea opined that only harm to Regeneron's 2 mg vial presentation of Eylea is relevant to the irreparable harm inquiry here and that any harm was quantifiable, reversible, or speculative.

B. Defendants May Launch Yesafili in the Absence of an Injunction

Biocon has announced it intends to appeal this Court's ruling that it infringes Regeneron's valid Product Patent. ECF No. 691 at 7 (stating Defendants' plan to file "an expedited appeal" of the Court's decision following the June 2023 trial "soon"). The parties attempted, unsuccessfully, to reach a stipulated injunction that would preserve the status quo in the marketplace during that appeal. Kayali Ex. 2 at 1, 3 (ECF No. 708-17); Kayali Exs. 3-4 (ECF No. 708-17). Absent an injunction, therefore,

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Defendants could launch Yesafili at the expiration of the temporary restraining order entered by this Court on May 17 (and extended on May 30). MDL ECF Nos. 107, 151. Regeneron seeks a permanent injunction preventing Defendants from producing, marketing, or selling their infringing product until the Product Patent expires in June 2027.

IV. GOVERNING STANDARDS

Plaintiff seeks a permanent injunction given the Court's findings on the '865 patent. This Court is authorized to award such equitable relief. See eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 390 (2006). Moreover, the Patent Act provides that in patent infringement cases, courts "may grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. In eBay, Justice Thomas set forth the standard for permanent injunctive relief:

> [A] plaintiff seeking a permanent injunction must satisfy a four-factor test before a court may grant such relief. A plaintiff must demonstrate: (1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction.

eBay, 547 U.S. at 391 (citations omitted). Even in patent litigation, this assessment must be made on a case-by-case basis and must be undertaken independently from a finding of infringement. See id. at 394. More specifically, eBay rejected the prior "categorical" approach where permanent injunctions necessarily followed a finding of patent infringement "absent exceptional circumstances." Id. at 391.[3] The patentee has the burden of proof on each factor. See eBay, 547 U.S. at 393-394; Nichia Corp. v. Everlight Americas, Inc., 855 F.3d 1328, 1341 (Fed. Cir. 2017) ("The movant must prove that it meets all four equitable factors.").

V. ANALYSIS

A. Irreparable Harm/Inadequate Damages

In assessing a request for a permanent injunction, courts often consider the first two eBay factors together. See, e.g., Acumed LLC v. Stryker Corp., 551 F.3d 1323, 1327 (Fed. Cir. 2008).

[3] To the extent Regeneron urges the Court to follow this "categorical" approach, this Court declines. Regeneron, in its papers, repeatedly insinuates a required automatic result here. Although, ultimately, the Court found each of the eBay factors sufficiently satisfied here after the required analysis, the Court likewise would not have hesitated to be the "first" to deny a motion for permanent injunction if the record did not justify such extreme equitable relief under applicable precedent, "historical practice" notwithstanding. Id. at 395 (Roberts, C.J., concurring).

Indeed, the core of an irreparable harm inquiry is the question whether legal remedies, such as monetary damages, could address the claimed injury or whether such damages are even calculable. Metalcraft of Mayville, Inc. v. The Toro Co., 848 F.3d 1358, 1368 (Fed. Cir. 2017); Celsis In Vitro, Inc. v. CellzDirect, Inc., 664 F.3d 922, 930 (Fed. Cir. 2012). Courts recognize multiple types of irreparable harm. See, e.g., Celsis In Vitro, 664 F.3d at 930 ("Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."). The Court will analyze each type of claimed harm in turn.

1. Appropriate Universe of Comparator Products To Assess Irreparable Harm

Initially, however, the Court must first assess which of Regeneron's aflibercept products and/or delivery mechanisms are appropriately considered in this analysis. Regeneron urges the Court to consider the potential impact of Yesafili on its entire catalogue of Eylea offerings. The Court declines to do so for the PFS presentation and Eylea HD. The Second Circuit explained the difference in the market between anti-VEGF medications presented in the form of a vial and those presented in the form of a PFS:

> For several years after they were first introduced, anti-VEGF medications [like aflibercept] were packaged into vials and

> administered in a two-step process. A doctor would first fill a syringe with medicine from an anti-VEGF vial and then inject the drug into a patient's eye. The newer versions of the medications are sold in prefilled syringes ("PFSs") and administered in one step. PFSs contain the same medication as vials but are injected directly into the patient's eye. This simpler process carries a significantly lower risk of complications and infections and is now the preferred way of administering anti-VEGF medications.

Regeneron Pharms., Inc. v. Novartis Pharma AG, 96 F.4th 327, 332 (2d Cir. 2024). [redacted]

Kevin Clark, Vice President of Regeneron's Ophthalmology Commercial Business Unit, asserts generally that the "launch of one or more infringing Eylea biosimilars would all but certainly reduce Eylea and Eylea HD's sales and market share in each and every market in which our products compete." (ECF No. 708-16, Clark Decl. ¶ 8; ECF No. 722-3, Birkos Decl. Ex. 6, Clark Dep. Tr. at 219:15–220:5 (opining that biosimilar aflibercept will "impact sales of the vial and the prefilled syringe")). Mr. Clark acknowledges, however, that he does not define a "market" or

"market share." (ECF No. 708-16, Clark Decl. ¶ 5 n.1). Dr. Sheridan likewise declined to define the market for the products at hand. (ECF No. 708-4, Sheridan Decl. ¶ 8 n.1).

Defendants take issue with Regeneron including all three Regeneron products (2 mg vial, 2 mg PFS, 114.3 mg/mL Eylea HD product) in its harm analysis. (ECF No. 722-1 at 6-8). Defendants note that Regeneron in antitrust litigation claimed that the 2 mg aflibercept market has distinct vial and PFS markets. (ECF No. 722-1 at 7 (citing Regeneron v. Novartis, 22-427 (2d Cir. June 10, 2022 (Doc. No. 65))). [redacted] Defendants' expert, Mr. Chris Spadea, explains that "Dr. Sheridan's failure to consider the market segmentation in his analysis, or consider other factors found in other non-asserted patents that may drive sales, makes his opinions unreliable and thus they should not be given weight in an analysis of irreparable harm in this matter." (ECF No. 722-18, Spadea Decl. ¶ 19).

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Regeneron responds that the market definition for antitrust purposes is a complex one based on whether a higher-priced product would cause a market switch. (ECF No. 747-2 at 4 n.3). Regeneron argues that where insurance coverage drives purchasing decisions, it is easier for Yesafili to take sales away from all of Regeneron's aflibercept products. (Id. at 4). Regeneron also urges that the Yesafili vial will compete directly with Eylea in a vial form. (Id.)

Regeneron asks the Court to consider whether products within the market "can both meet the same needs," Broadcom v. Emulex, 2012 WL 13036855, at *3 (C.D. Cal. March 16, 2012), or "compet[e] for the same customers in the same markets," Presidio Components, Inc. v. Am. Tech. Ceramics Corp., 702 F.3d 1351, 1363 (Fed. Cir. 2012). (ECF No. 747-2 at 3-4). Regeneron urges that all its products are "treating the same diseases in the same way," and that Yesafili will be attractive to existing "Eylea" customers due to having the same "dosing schedule, safety, and effectiveness." (ECF No. 747-2 at 5).

Defendants urge that the actual claims asserted as part of the infringement judgment were each limited to a 40 mg/mL "vial." Defendants seem to agree that doctors will find Yesafili attractive to prescribe but have noted that dosing schedule benefits are tied

to dosing patents that this Court's Trial Decision invalidated, and that drug potency and performance benefits originate with the aflibercept molecule itself, the patents to which have expired. (ECF No. 722-1 at 5-6, 16; Trial Decision at 46-50, 312-13). Defendants' position also is consistent with [redacted]

The Court finds that the claims that were the subject of the Court's Trial Decision were not directed to the aflibercept molecule generally, but to "a vial" specifically, not a PFS.

a. 2 mg vial vs. 2 mg PFS.

The '865 patent claims Regeneron asserted against Defendants were limited to vials at 40 mg/mL concentration (i.e., the 2 mg vial product). The '865 patent itself does not equate a PFS and a vial; it treats them as separate products. (See, e.g., ECF No. 1-17, '865 patent at 5:24 ("pre-filled syringe ***or*** vial" (emphasis

added)). Claims that Regeneron ***did not*** assert against Defendants had elements to a PFS. (See id. at 20:65–21:12 (PFS claims)). That is further support that the marketing and sales of the two products should be considered independently. Also supporting this position is that before the Second Circuit, Regeneron took the position that the 2 mg vial and 2 mg PFS products reflected distinct markets for antitrust purposes since the PFS provided added safety benefits. (ECF No. 722-8, Birkos Decl. Ex. 9, Regeneron Opening Br. at 29, Regeneron v. Novartis, 22-427 (2d Cir. June 10, 2022) (Doc. No. 65) ("PFS treatments have important practical and medical benefits that distinguish them from alternative treatment methods, including vials")).

[redacted] Regeneron told the Second Circuit that "independent analysts, leading medical journals," and other data showed a reduction in side

effects and preparation time from using a PFS instead of a vial. (ECF No. 722-8, Birkos Decl. Ex. 9, Regeneron Opening Br. at 30, Regeneron v. Novartis, 22-427 (2d Cir. June 10, 2022) (Doc. No. 65)). The Second Circuit's explanation above likewise adopted the reasoning on the added safety and convenience that a PFS provides over a vial. Nor does it appear that Regeneron has discovered the PFS no longer provides any benefits worth marketing; [redacted] ECF No. 722-8, Ex. 9, Regeneron Opening Br. at 1-2, Regeneron v. Novartis, 22-427 (2d Cir. June 10, 2022) (Doc. No. 65) (Regeneron telling the Second Circuit that the PFS gives "more accurate dosing, require[s] fewer steps to administer, and reduce[s] the risk of severe complications, such as inflammation."); id. at 2 ("physicians now overwhelmingly prefer and prescribe . . . PFS")).

Thus, the 2 mg vial and 2 mg PFS represent distinct customer markets, and the PFS meets a different need or administration preference compared to the vial.

b. 2 mg vial vs. Eylea HD

For Eylea HD, it is again important to start with what the asserted claims state. As noted above, claim 2 limited all asserted claims to a 40 mg/mL concentration (i.e., the 2 mg vial). Regeneron confirms that Eylea HD is not a 40 mg/mL concentration, but a much higher 114.3 mg/mL concentration. (ECF No. 708-16, Clark Decl. ¶ 3).

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[redacted] Regeneron's briefing also carefully argues that Yesafili would compete with "Eylea," not the full franchise that includes "Eylea HD." (ECF No. 747-2 at 5-6). [redacted]

Thus, on the present record, the market for the Eylea HD product is distinct from the market for the aflibercept 2 mg (40 mg/ml) vial product as well.

Given the above and other record evidence considered, the 2 mg aflibercept vials, 2 mg aflibercept PFS, and the 8 mg Eylea HD products represent distinct products and markets for purposes of assessing irreparable harm.

2. Lost Market Share

However, the direct competition between Yesafili and Regeneron's Eylea 2 mg vial alone adequately supports a finding of irreparable harm. [redacted] That is a significant volume of sales, by any measure. Even if the rest of Regeneron's sales were somehow immune from harm, [redacted] is a valuable part of its business, and any competitive threats to it are significant.

Defendants argue that Regeneron's lost market share is quantifiable and that legal remedies are adequate to compensate Regeneron. This Court disagrees. Courts regularly recognize that being "forced to compete against products that incorporate and infringe [one's] own patented inventions" creates irreparable harm. Douglas Dynamics, 717 F.3d at 1345. Defendants' cited cases (Opp. 17) do not support their position. Unlike the patentee in Praxair, Inc. v. ATMI, Inc., Regeneron "described . . . specific sales [and] market data to assist the court" and explained "why it may have difficulties calculating damages going forward." 479 F. Supp.2d 440, 444 (D. Del. 2007). In Philip Morris Prods. S.A. v. R.J. Reynolds Vapor Co., the district court found the patentee had

not shown a monetary remedy was insufficient because the patentee "did not have a significant market before [the defendant] infringed its patent." 2023 WL 2843796, at *5 (E.D. Va. Mar. 30, 2023), appeal dismissed sub nom. RAI Strategic Holdings, Inc. v. Altria Client Servs. LLC, 2024 WL 413427 (Fed. Cir. Feb. 5, 2024). That is far from the case here. The Court also recognizes that early infringing competition can alter market dynamics moving forward in a way that cannot be unwound, giving Defendants a "competitive foothold" they would not otherwise have had and which cannot be fully quantified and remedied by damages. Indivior Inc., 2018 WL 3496643, at *12. This is classic irreparable harm. Thus, this Court concludes that Regeneron has shown its likely harm due to lost market share and sales is not fully addressable through legal or monetary remedies.

3. Price Erosion

Again, "price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." Celsis In Vitro, Inc., 664 F.3d at 930 (citing Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1362 (Fed. Cir. 2008); Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1382-83 (Fed. Cir. 2006)).

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When a competing product launches, the patented product often must drop its price to remain competitive. Courts consistently recognize this drop in price as a source of irreparable harm. See, e.g., Celsis In Vitro, 664 F.3d at 930 (affirming "price erosion" as source of "permanent, irreparable harm"); Sanofi-Synthelabo, 470 F.3d at 1383 n.9 (same); Abbott Lab'ys, 544 F.3d at 1362 (same).

"The phenomenon of price erosion in the pharmaceutical industry is well known." Hoffmann-La Roche Inc. v. Cobalt Pharms. Inc., 2010 WL 4687839, at *12 (D.N.J. Nov. 10, 2010), modified, 2012 WL 458435 (D.N.J. Feb. 9, 2012). And "[p]rice erosion is most likely to occur in cases . . . in which no generic competitors have yet entered the marketplace, placing the patentee in an exclusive position." Id.

Price erosion is typically irreversible even if the infringing product exits the market, because returning prices to pre-infringement levels risks loss of goodwill and reputation with payors and customers. Sanofi-Synthelabo v. Apotex Inc., 488 F. Supp.2d 317, 343 (S.D.N.Y. 2006) (patentee would be "harmed by loss of consumer good will by customers who will have grown accustomed to lower prices" if it restored pre-infringement

pricing), aff'd, 470 F.3d 1368; Celsis In Vitro, 664 F.3d at 930 (same).

Regeneron has also shown that Yesafili's launch will cause Eylea's price to erode. See Clark Decl. ¶¶ 8-10; Sheridan Decl. ¶ 62. [redacted]

a. The launch of a biosimilar typically causes price erosion

Researchers who study biosimilars, including Defendants' own expert Dr. Ivo Abraham, have found repeatedly that biosimilars' launching causes the reference product to lower its prices. Abraham Dep. Ex. 5 at 6-12. That is because a biosimilar's launch creates a commodity market — one in which products (here, Yesafili and Eylea) have "full or substantial fungibility" with each other. Abraham Dep. Ex. 13 at 1. And because biosimilars are generally priced lower than the reference product, the reference product's manufacturer typically must lower its own prices to stem sales losses. Sheridan Decl. ¶¶ 66-69, 77-84; [redacted] As Dr. Abraham confirmed, "[i]t is a generally accepted perspective that commercialization [of a biosimilar] lowers prices" of the reference product. Abraham Tr. 123:17-18.

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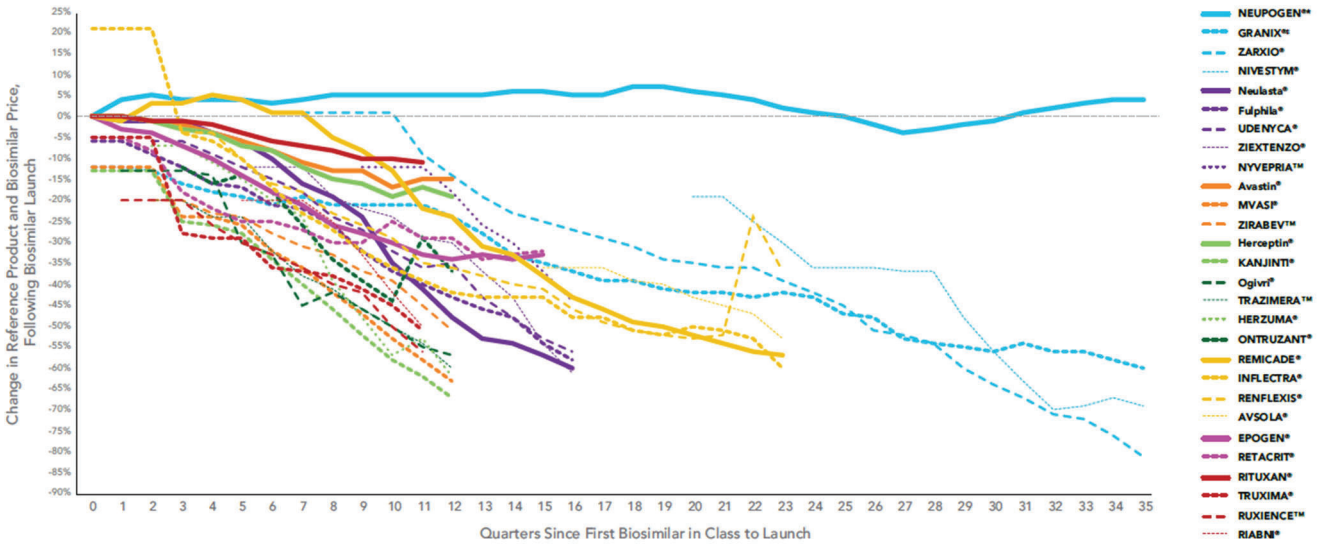
[redacted] The WAC is the price a drug manufacturer lists, not including any discounts, rebates, or negotiated price reductions. Id. ¶ 35. Biosimilars launch at an Average Sale Price (ASP) — the average price that manufacturers charge purchasers after discounts and rebates — that is [redacted]

When other biosimilars have launched — such as biosimilars for Neulasta, trastuzumab, and bevacizumab — the ASP for the reference drug began to decline immediately and never recovered. Abraham Tr. 124:1-2 (discussing price erosion of Neulasta upon launch of its biosimilars); Abraham Dep. Ex. 5 at 7 (discussing price erosion of reference drugs upon launch of trastuzumab and bevacizumab biosimilars); Abraham Tr. 126:16-128:16 (same).

Samsung Bioepis's Biosimilar Market Report for Q1 2024 states that "[b]iosimilar launches have led to significant price decreases over time," and "[o]n average, ASP declined by 41% three years . . . post first biosimilar launch with more mature markets

demonstrating increasing price concessions." Sheridan Ex. 33 at 12 (ECF No. 708-7).

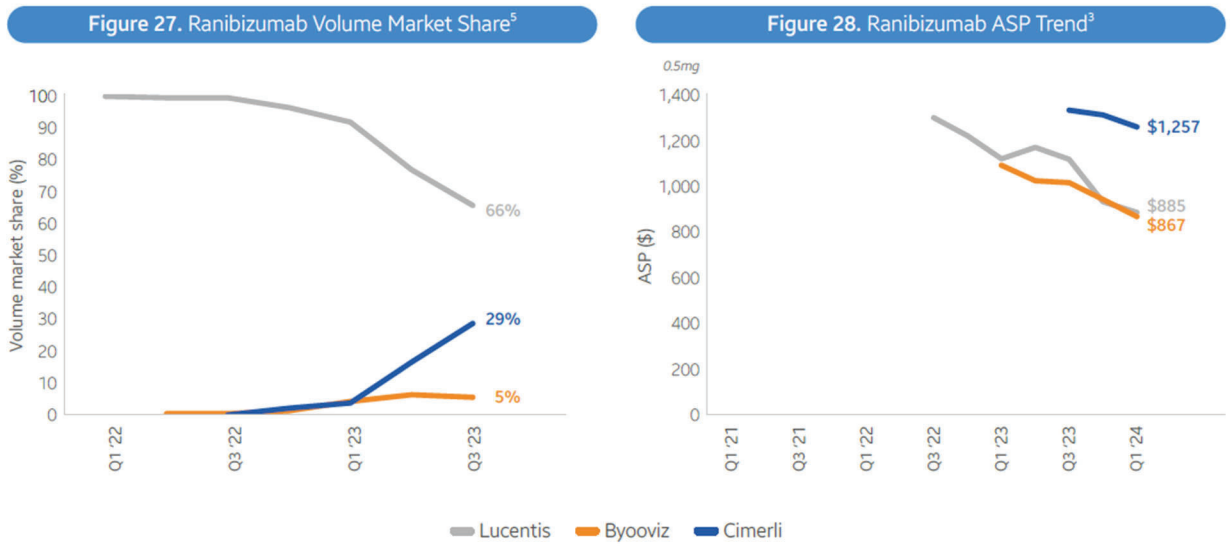
Amgen has observed the same trend, stating in its 2022 Biosimilars Trend Report that the ASP "for both reference products and biosimilars" "is declining, due to competition." Sheridan Ex. 52 at 6 (ECF No. 708-9); see Sheridan Decl. ¶ 39. This same report shows that biosimilar prices "have decreased at a negative compound annual growth rate . . . of -9% to -24%," and "[t]he prices of most reference products have decreased at a negative [compound annual growth rate] of -4% to -21%." Sheridan Ex. 52 at 6. Amgen's 2022 Report contains a graph illustrating the trend in reference products' declining ASP following the launch of biosimilars:



Id. at 13 (Fig. 5); Sheridan Decl. ¶ 39.

Ophthalmic drugs are not immune from this trend, as the launch of ranibizumab biosimilars has shown. See Sheridan Decl. ¶ 41; Sheridan Ex. 33 at 9 ("Recent ranibizumab biosimilar launches have already led to lower reference product ASP costs."). When these biosimilars entered the market, Genentech, the maker of the branded biologic Lucentis, was forced to reduce its ASP to or below the ASPs of the competing biosimilars. Sheridan Decl. ¶ 41. As of Q1 2024, the ASP of all ranibizumab products has declined 23% since the biosimilars' launch. Sheridan Ex. 33 at 22. Despite these price reductions, Lucentis continued to lose significant market share to ranibizumab biosimilars; as of Q3 2023 the two ranibizumab biosimilars hold a combined market share of 34%. Id.

The figures below, featured in Samsung Bioepis's 2024 Market Report, illustrate the decline in Lucentis's ASP and market share that ranibizumab biosimilars caused:



Id. (Figs. 27 & 28).

b. Regeneron will likely experience price erosion if Yesafili launches

The downward pricing pressure Eylea will face after Yesafili's launch is different in kind from ordinary, non-biosimilar competition with other anti-VEGF medications. Almost across the board, biosimilars lead to permanent price erosion of the reference drug. That is because their launch causes the reference drug to compete for the first time with *a* highly similar version of itself. The same will happen with Eylea if Yesafili is permitted to launch.

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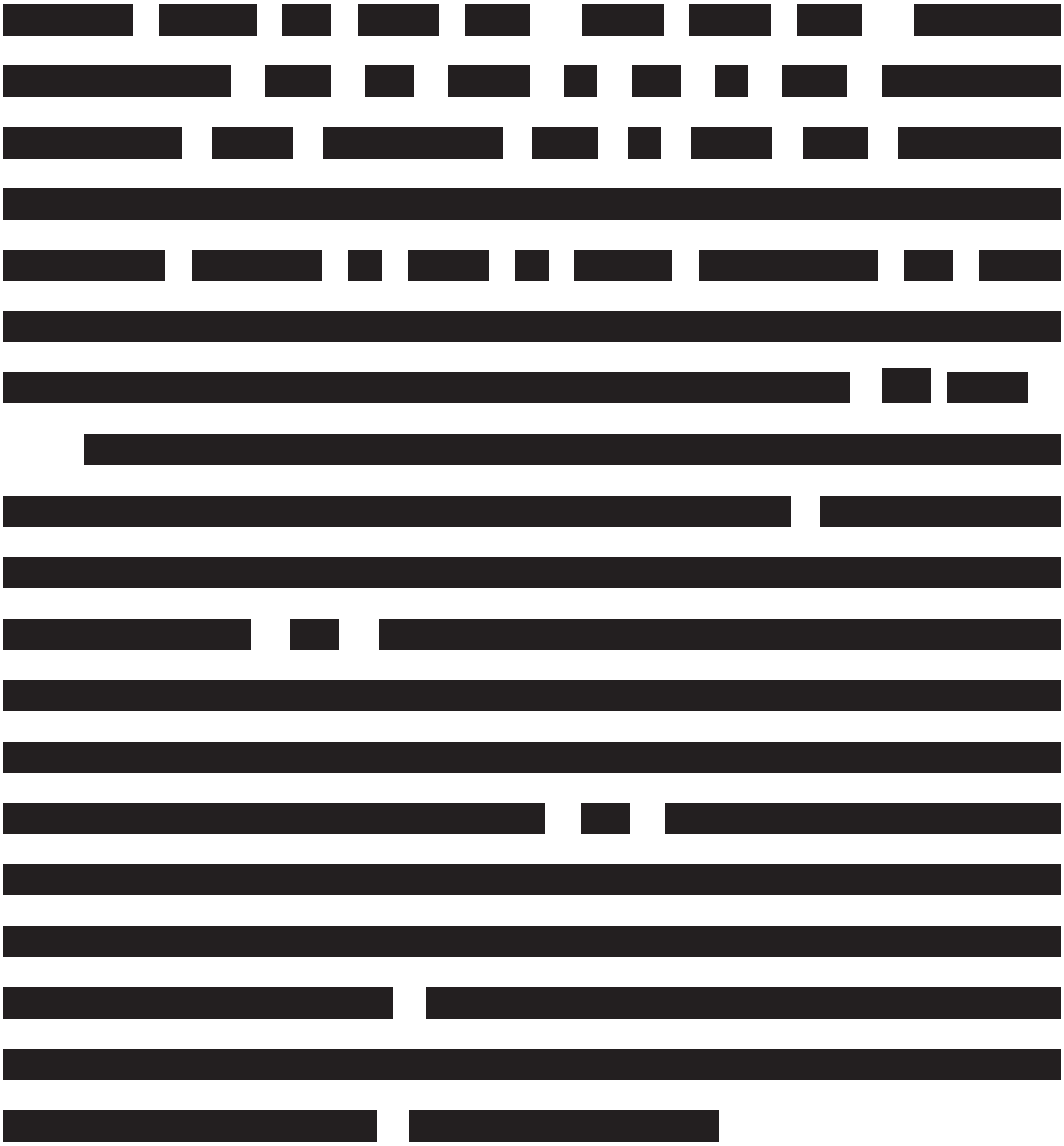
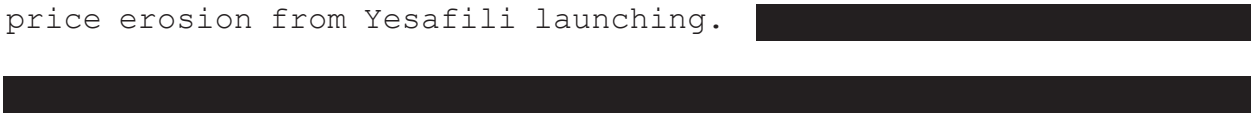


Defendants' evidence confirmed Eylea will likely experience price erosion from Yesafili launching.



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[redacted] Defendants' expert, Mr. Spadea, did not consider [redacted] in offering his opinion about price erosion, [redacted] Because [redacted] are a more reliable estimate of [redacted], the Court finds that Mr. Spadea's price erosion analysis is incomplete and less reliable than the evidence Regeneron offered.

Further, if Regeneron is forced to lower prices on Eylea because of biosimilar entry, such price erosion will likely be permanent. [redacted]

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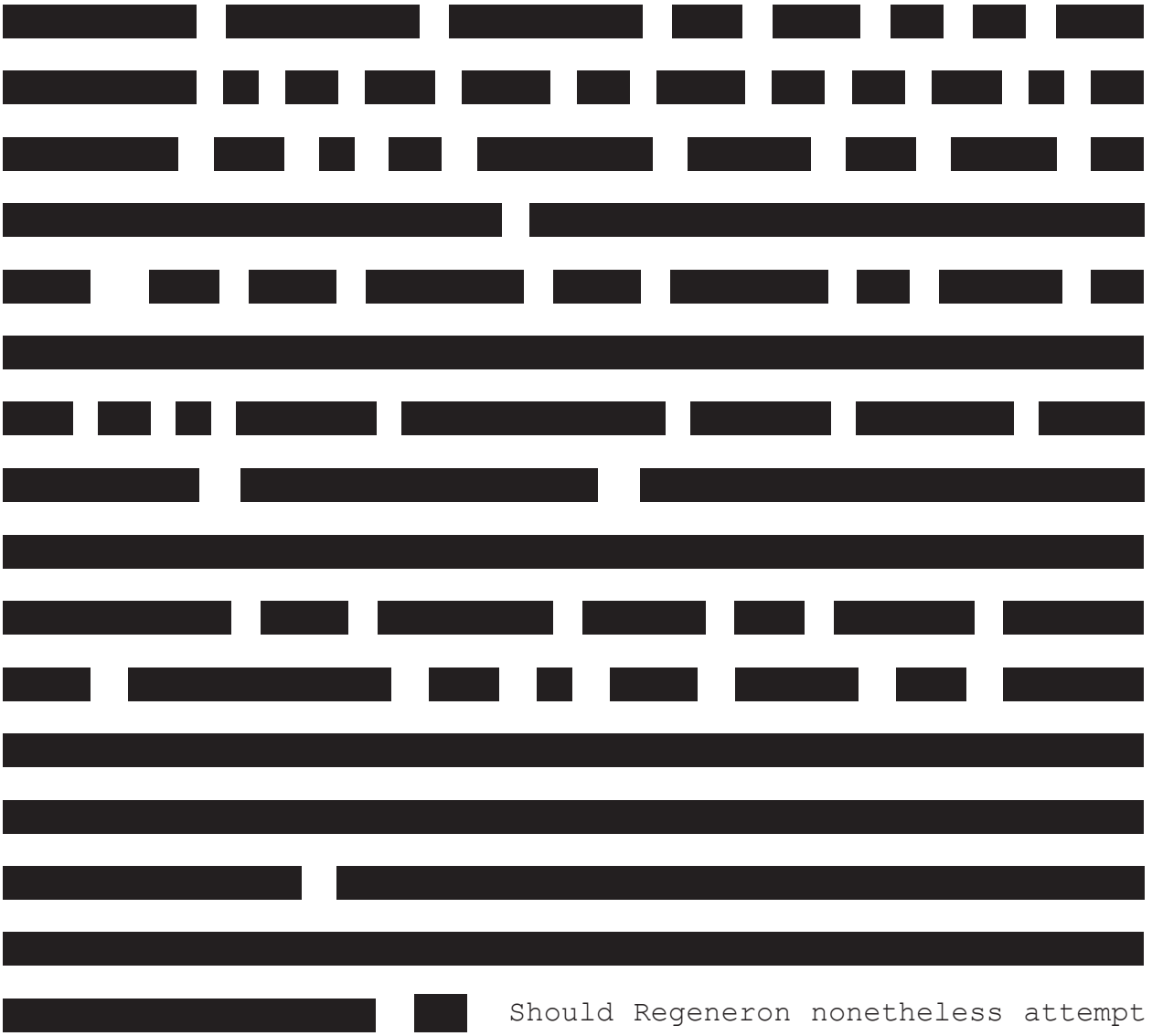

Should Regeneron nonetheless attempt to revert prices on Eylea to their original values despite the foregoing, it would suffer further harm in the form of reputational damage and loss of goodwill.

Given this ample evidence in the record showing declines in reference product pricing following a biosimilar's launch, and the evidence of Defendants' plans in particular, the Court finds that

Regeneron is likely to suffer price erosion if Yesafili is permitted to launch. And based on this same body of evidence, the Court finds that the price of Regeneron's Eylea is unlikely to return to pre-launch levels even if Yesafili is later taken off the market following Defendants' appeal in this case.

[redacted] Historically, biosimilars have launched at below the reference product's price, which often causes reference products to lower the price in order to compete. Id. It is unlikely that Yesafili will be an exception to the general trend. [redacted]

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[redacted] This evidence confirms that Regeneron will likely have to lower the price of its Eylea products if Yesafili launches. [redacted] "[p]rice erosion is most likely to occur in cases . . . in which no generic competitors have yet entered the marketplace, placing the patentee in an exclusive position." Hoffmann-La Roche Inc., 2010 WL 4687839, at *12. Currently, Regeneron is the only company with an aflibercept product on the market, [redacted]

The term "price erosion" sounds of economic loss and not necessarily the type of irreparable harm required under eBay. Regardless, the Federal Circuit has upheld findings of irreparable harm based on evidence that the infringer offered "significantly discounted prices," forcing the patentee to lower its prices to compete. Celsis In Vitro, 664 F.3d at 930. Regeneron has shown

that it will experience the same harm here. Thus, based on the consistent recognition that such a price drop is a source of irreparable harm, this Court holds that allowing Defendants to launch Yesafili would irreparably harm Regeneron.

Additionally, Regeneron's irreparable harm from price erosion would be irreversible even if Yesafili lost its appeal from trial in this case and left the market. For one, contractual price concessions would be locked in for at least the terms of the contracts. And, because Medicare reimbursement rates lag market pricing, future price increases would leave physicians paying a higher rate to purchase Eylea than they were being reimbursed. In short, Regeneron could only raise its prices by risking the "loss of consumer good will by customers who will have grown accustomed to lower prices." Sanofi-Synthelabo, 488 F. Supp. 2d at 343.

Given the evidence in the record, the Court concludes that Regeneron's claim of price erosion is not merely speculative. This case is dissimilar from Integra Lifesciences Corp. v. Hyperbranch Medical Technology, Inc., which Defendants cite (Opp. 13), where the allegedly infringing product had already launched, and six months after the plaintiff filed a motion for a preliminary injunction, it still could not demonstrate any lost market share or price erosion. 2016 WL 4770244, at *13 (D. Del. Aug. 12, 2016).

Nor is it like SmartSky Networks, LLC v. Gogo Business Aviation, LLC (Opp. 13), where the patentee dropped its prices before the infringer announced its prices and the patentee's expert "offered no economic analysis other than conclusory assertions, to support its price erosion theory." See 2024 WL 358136, at *5 (Fed. Cir. Jan. 31, 2024).

The harms to Regeneron from price erosion, as the Federal Circuit has recognized, are also not sufficiently calculable or compensable. The evidence shows that it will be nearly impossible to calculate and fully compensate for price erosion. This is because, in part, the price erosion will extend beyond any damages period and may impact future price negotiations in unquantifiable ways. Id.

In summary, the Court finds that price erosion prompted by Yesafili's launch would cause Regeneron irreparable harm.

4. Reputational Injury

Reputational injury is also a well-recognized form of irreparable harm. Douglas Dynamics, 717 F.3d at 1344-45. This can occur when doctors or patients know that a patentee is responsible for removing an available drug. AstraZeneca LP v. Apotex, Inc., 623 F. Supp.2d 579, 613 (D.N.J. 2009) ("AstraZeneca claims that an unauthorized launch by Apotex (followed by a

subsequent exit) would result in intangible and unquantifiable damage to AstraZeneca's reputation and goodwill. For example, they assert that doctors who would have prescribed Apotex's BIS may blame AstraZeneca for the sudden unavailability of Apotex's generic BIS once Apotex is forced to leave the market. . . . The Court agrees that an unauthorized launch by Apotex would have some intangible effects on AstraZeneca's goodwill."), supplemented, 623 F. Supp. 2d 615 (D.N.J. 2009), aff'd, 633 F.3d 1042 (Fed. Cir. 2010); see also Baxalta Inc. v. Genentech, Inc., 2018 WL 3742610, at *11 (D. Del. Aug. 7, 2018) (where defendant already launched its product before the preliminary injunction hearing, patentee would suffer reputational harm when doctors would know that patentee was responsible for removing an available drug).

Regeneron has also established that it will suffer reputational harms in the pharmaceutical community and among healthcare professionals if Yesafili is permitted to launch but later is removed from the market. If a biosimilar launches and then is taken off the market as a result of litigation, providers and, most importantly, patients will blame Regeneron for the loss of their chosen treatment. Sheridan Decl. ¶¶ 85-87; Sheridan Tr. 63:17-65:5, 139:2-8. Here, the trial has already taken place, but Defendants will appeal as soon as they are able. Unlike a course

of antibiotics or a temporary pain-relief medication, patients must take aflibercept regularly for a long period of time. Trial Tr. 137:3-14 (Yancopoulos). Yesafili's removal from the market after affirmance, once it has been administered to perhaps thousands of patients, will disrupt these patients' course of treatment. Not only may patients feel uncomfortable switching medication mid-course, but they will also have to seek approval from private insurers and Medicare and Medicaid for a different product, a process likely to interrupt their treatment schedule. Sheridan Decl. ¶ 87. The Court finds that this harm to Regeneron's relationships with its customers and their treatment regimens would be a likely result of Yesafili's launching.

Regeneron has established that it will suffer such irreparable harm from reputational injury if Yesafili is permitted to launch now. See Douglas Dynamics, 717 F.3d at 1344-45. Were Yesafili to launch and then later exit the market, patients and doctors would know that Regeneron was responsible for removing the available drug and would likely be upset given the disruption of losing their preferred treatment. See AstraZeneca, 623 F. Supp.2d at 613. Because Regeneron has demonstrated that it likely would be blamed for removing Yesafili from the market — should Yesafili launch and then have to exit following a judgment for

Regeneron — Regeneron has demonstrated irreparable reputational harm.

5. Impairment of R&D Funding

Regeneron also suggests, as a separate form of irreparable harm, that its research and development (R&D) funding and spending will be negatively affected if Yesafili launches. The Court rejects this as a basis of irreparable harm here.

Regeneron's Mr. Clark states that Regeneron is committed to future R&D funding, and that "any harm to Regeneron's sales of Eylea and Eylea HD would necessarily impinge on the amount of money available for investment into research." (ECF No. 708-16, Clark Decl. ¶ 19). Dr. Sheridan does not address this topic as evidence of irreparable harm. Regeneron in its briefing argues that biosimilars "will reduce revenues from its flagship product, and thereby reduce the money available to support its research and development efforts." (ECF No. 708-3 at 12). Regeneron argues that loss of R&D investment has routinely been held to serve as a basis for finding irreparable harm. (Id.)

Defendants respond that Mr. Clark's suggestion that Regeneron will lack R&D funds for its projects if an aflibercept biosimilar launches contradicts what Regeneron has said in public statements and to investors. (ECF No. 722-1 at 19-20). As recently as March

6, 2024, when Regeneron was asked what it would do with the "now $16 billion of cash" Regeneron has amassed, an amount that is "only getting larger," Regeneron answered, that "I think you're going to see us continue to fund our pipeline in a very meaningful way. Obviously, we have plenty of resources to do that . . . . [W]e're looking for opportunities . . . to deploy our cash just because we have a lot of it."[4] Regeneron told the SEC they expected to continue increasing R&D expenditures. (ECF No. 708-16, Ex. 14 at 91). [redacted] Defendants urge that Mr. Clark himself confirmed that robust competition in this field has not harmed Regeneron's ability to bring new products to market. (ECF No. 722-3, Ex. 6, Clark Dep. Tr. at 50:19 – 51:5). Defendants also noted that when they previously deposed Dr. Yancopoulos before trial, he was unable to articulate any research project that might be put on hold if Yesafili were to enter the market. (ECF No. 722-3, Ex. 4, Yancopoulos Dep. Tr. at 53:15-24

[4] ECF No. 722-14, Ex. 28, Regeneron Pharmaceuticals, Inc. (REGN) TD Cowen 44th Annual Health Care Conference Call Transcript (Mar. 6, 2024) at 10.

(Yancopoulos saw no documents and CEO never informed him Regeneron would cut back on R&D if Mylan product on the market)).

Regeneron responded that even if it has the funds to continue "**some** R&D programs — it will fund less if it is deprived of hundreds of millions of dollars by Defendants' infringement," and because other competitors may be "emboldened by one premature launch to also launch," as in Amgen v. F. Hoffmann-LaRoche, 581 F. Supp. 2d 160, 212 (D. Mass. 2008). (ECF No. 747-2 at 10).

The Court finds that Regeneron has not met its burden with this element of claimed irreparable harm. The Federal Circuit cautioned against allowing generalized assertions that loss of revenue would lead to a loss of research and development opportunities because

> that claim of injury is not materially different from any claim of injury by a business that is deprived of funds that it could usefully reinvest. If a claim of lost opportunity to conduct research were sufficient to compel a finding of irreparable harm, it is hard to imagine any manufacturer with a research and development program that could not make the same claim and thus be equally entitled to preliminary injunctive relief. Such a rule would convert the "extraordinary" relief of a preliminary injunction into a standard remedy, available whenever the plaintiff has shown a likelihood of success on the merits.

Eli Lilly & Co. v. Am. Cyanamid Co., 82 F.3d 1568, 1578 (Fed. Cir.

1996) (affirming denial of injunction against generic drug competitor). This principle also differentiates Amgen. In Amgen, the district court noted that Amgen's infringed patents were directed to "the source" of "what enables mass production and commercial viability" of the drug at issue. 581 F. Supp.2d at 195. The patents also were "admittedly 'the foundation of Amgen's business,'" and any question into their value or ability to keep other competitors off the market would cause Amgen to lose access to research and development funds. Id. at 212. Regeneron's cited cases also do not support a finding of irreparable harm. In Mylan Institutional, for example, there was evidence of record that the harm to R&D would result from the loss of "half or more of [patentee's] revenue," [redacted]. See Mylan Institutional LLC v. Aurobindo Pharma Ltd, 2016 WL 7587325, at *23 (E.D. Tex. Nov. 21, 2016). The same is true of Regeneron's Janssen case. See Janssen Prods., L.P. v. Lupin Ltd., 109 F. Supp. 3d 650, 697 (D.N.J. 2014) (irreparable harm where evidence indicates "Janssen would lose 70 to 80 percent of its sales upon a generic launch").

That is not applicable here, [redacted]

[redacted] Regeneron's analysis is essentially that it would like more funds to usefully invest, which is not enough under the Federal Circuit precedent noted above. Therefore, Regeneron's claimed impact on R&D prospects finds no basis in either fact or law, and the Court does not rely upon it in issuing the permanent injunction.

6. Causal Nexus

To obtain a permanent injunction, a patentee must show "some causal nexus between [a defendant's infringement] and [the] alleged harm" — i.e., "show that the patentee is irreparably harmed **by the infringement**." Apple Inc. v. Samsung Elecs. Co., 735 F.3d 1352, 1363-64 (Fed. Cir. 2013) ("Apple III").

In cases involving "complex, multi-featured" products, such as "smartphones and tablets," where consumer demand is driven by some features of the finished good and not others, this nexus analysis can be complicated. Id. at 1362; see also Genband US LLC v. Metaswitch Networks Corp., 861 F.3d 1378, 1384 (Fed. Cir. 2017)

(discussing "the causation approach suitable for a multi-feature, multi-purchaser context"). In such cases, a patentee must show "some connection between the patented feature and demand" for the accused product, though it need not "show that a patented feature is the exclusive reason for consumer demand." Apple III, 735 F.3d at 1364.

The nexus inquiry can be much simpler for products that "ha[ve] a small number of features," like medications. Id. at 1361-62. That is because the nexus inquiry has "little work to do . . . when the infringing product contains no feature relevant to consumers' purchasing decisions other than what the patent claims." Genband, 861 F.3d at 1384, n.2. Accordingly, the multi-feature nexus analysis is straightforward for patents that cover the product itself instead of a "feature" or "attribute[] of the finished consumer good" because "it is not possible to separate" the patent "from the product itself in evaluating consumer demand and nexus." Janssen Prods., 109 F. Supp. 3d at 700. In such cases, nexus is "apparent." Genband, 861 F.3d at 1384 n.2. If the "Patent encompasses nearly the entire Device[, then] . . . Demand for the Device can fairly be described as demand for the Patent." Apnea Scis. Corp. v. Koncept Innovators, Inc., 2016 WL 9086937, at *6 (C.D. Cal. Nov. 7, 2016); see also Power

Probe Grp., Inc. v. Innova Elecs., Corp., 2023 WL 7043388, at *13 (D. Nev. Oct. 25, 2023) (distinguishing multi-featured nexus inquiry because "Plaintiff's patent encompasses the entire product at issue, not merely a feature, and Plaintiff's evidence that it will likely suffer irreparable harm absent an injunction demonstrates the requisite causal nexus").

Applying the above principles to the pharmaceutical context, the nexus requirement is satisfied if a manufacturer "would not be able to make the products proposed in its" regulatory filing without infringing the asserted patents. Janssen Prods., 109 F. Supp. 3d at 699; see also Mylan Inst'l LLC v. Aurobindo Pharma Ltd., 857 F.3d 858, 873 (Fed. Cir. 2017) (upholding nexus finding because "[w]ithout infringing the . . . patents" defendants "would not be able to make the . . . product described in its ANDA") (internal quotation marks omitted).

If the connection between the infringed patent and the harm is undeniable, courts often find irreparable harm without discussing the nexus factor. See Metalcraft of Mayville, 848 F.3d at 1368-69 (affirming the grant of a preliminary injunction after reciting, but not discussing, the nexus requirement of the irreparable harm factor); see also In re Depomed Pat. Litig., 2016 WL 7163647, at *78 (D.N.J. Sept. 30, 2016), aff'd sub nom.

Grunenthal GMBH v. Alkem Lab'ys Ltd., 919 F.3d 1333 (Fed. Cir. 2019) (finding irreparable harm after reciting, but not discussing, the nexus requirement).

This Court finds that Regeneron has shown "some causal nexus between [Defendants' infringement] and [the] . . . alleged harm," which is sufficient to demonstrate that Regeneron "is irreparably harmed by the infringement." Apple III, 735 F.3d at 1363.

Defendants' Yesafili product is not a "complex, multi-featured" product, where consumer demand is driven by some features of the finished product and not others. Id. at 1362. In Apple III, for example, the patentee sought to enjoin the sale of various smartphones and tablets, and the patents at issue were directed to specific features of those devices, like pinch-to-zoom and double-tap-to-zoom functionalities that allow users to navigate the display screens. Id. at 1358. Yesafili does not have analogous segregable features that one can mentally divide and then ask: "Is this a feature that drives demand?" There is no "feature" that parallels, for example, a double-tap to zoom gesture on a smart phone. Thus, Regeneron need not show the specific "connection between the patented feature and demand" that is required in cases involving multi-featured products. Id. at 1364.

In other words, the nexus inquiry has "little work to do" here because Yesafili "contains no feature relevant to consumers' purchasing decisions other than what the patent claims," which is the drug product. Genband, 861 F.3d at 1384, n.2. The multi-feature nexus analysis does not apply to the Product Patent because its claims cover Yesafili itself — a 40 mg/mL ophthalmic formulation containing aflibercept that has recited purity recited in the claims — not a "feature" or "attribute[] of the finished consumer good." Janssen Prods., 109 F. Supp. 3d at 700. Indeed, in assessing another nexus question, the Court previously noted that there was a connection between the Product Patent's claims and certain unexpected properties because Eylea exhibited those properties and Eylea "is the invention disclosed and claimed in the [Product] patent." ECF No. 664 at 197. So too here. The claims require a vial comprising aflibercept, an organic co-solvent, a buffer, and a stabilizing agent and 98% native conformation as measured by size exclusion chromotography. Defendants' Yesafili product — not a component or feature thereof — is the subject of the infringed claims. ECF No. 692 at 74. As a result, "it is not possible to separate" the Product Patent "from the product itself in evaluating consumer demand and

nexus." Janssen Prods., 109 F. Supp. 3d at 700. Thus, nexus is "apparent." Genband, 861 F.3d at 1384 n.2.

In yet another framing of this concept as applied to the pharmaceutical context, the nexus requirement is satisfied here because Defendants "would not be able to make the products proposed in its" BLA without infringing the Product Patent. Janssen Prods., 109 F. Supp. 3d at 700. This Court has already held that Defendants' BLA Product infringes the asserted claims of the Product Patent. ECF No. 664 at 113; see also PTX-1541. Defendants have not offered evidence that they have sought, let alone received, FDA approval to manufacture any alternative biosimilar aflibercept products that do not infringe. Because "without infringing the . . . patents" Defendants "would not be able to make the . . . product described in" their BLA, Defendants' infringement is a prerequisite to Yesafili's sales and causes Regeneron's harm. Mylan Inst'l, 857 F.3d at 873.

The nexus requirement is thus satisfied.

B. Balance of Equities

This third injunctive relief factor requires the court to balance the harm an injunction would cause to the party opposing an injunction with the harm the movant would suffer should the requested injunction be denied. See Robert Bosch LLC v. Pylon

Manufacturing Corp., 659 F.3d 1142, 1156 (Fed. Cir. 2011). In performing this balancing of hardships, the court considers only the harm to the parties, not to the interests of third parties such as customers or patients. Acumed, 551 F.3d at 1330.

Regeneron contends that, absent injunctive relief, Defendants will launch Yesafili and compete directly with Regeneron, placing a substantial hardship on Regeneron. ECF No. 708-1 at 6-13. Regeneron argues that such sales of Yesafili will cause it to suffer irreparable harms, including market share erosion, price erosion, disruption of payor relationships, harm to the commercial trajectory of Regeneron's Eylea HD product,[5] reputational harm, and loss of research and development funding. Id. Regeneron submits testimony from Mr. Clark and Dr. Sheridan to substantiate those harms. Clark Decl. ¶¶ 6-19; Sheridan Decl. ¶¶ 60-101.

Defendants argue they will suffer lost sales if an injunction is entered. [redacted] Regeneron does not

[5] Again, the Court does not consider impacts upon Eylea HD in its analysis.

dispute that at least some sales will be lost if an injunction is entered. Defendants also suggest the Court should consider in its balancing analysis that (i) Regeneron already has "secured over 12 years of regulatory exclusivity, and significant compensation beyond its R&D investment," Opp. 21, (ii) Regeneron "has been acutely aware of, and planned for, biosimilar competition upon expiration of Eylea's regulatory exclusivity in May 2024," id., (iii) Regeneron is engaged in pending litigation regarding alleged kickbacks and payments to key opinion leaders to incentivize Eylea prescriptions, id. at 21 n.8, and (iv) denial of an injunction would "dampen[]" "manufacturers' incentives, to invest in biosimilars going forward," id. at 22.

Regeneron responds that lost sales of Yesafili are not harms that should be given weight in the balance of hardships analysis, as they would be sales of a product found to infringe Regeneron's patent rights. ECF No. 747-2 at 11 (citing Qualcomm, 543 F.3d at 704).

The Court finds the balance of hardships favors the requested injunctive relief here. As described above, the Court finds that the launch and continued sale of Yesafili in the absence of an injunction will result in direct competition between Defendants and Regeneron and cause harms to Regeneron that cannot be fully

calculated, quantified, or compensated by remedies available at law. See Sheridan Decl. ¶¶ 60-101. Forcing a patentee to compete directly with its patented technology results in substantial hardship for the patentee. See Robert Bosch, 659 F.3d at 1156 ("requiring [the patentee] to compete against its own patented invention, with the resultant harms described above, places a substantial hardship on [the patentee]."); Hafco Foundry & Mach. Co. v. GMS Mine Repair & Maint., Inc., 2018 WL 1786588, at *4 (S.D.W. Va. Apr. 12, 2018) (patentee "will be forced to compete against its own patent, in itself, a significant hardship"). Absent an injunction, Defendants will launch and sell Yesafili, and those sales will cause Regeneron to suffer market share erosion, price erosion and disruption of payor relationships. See Clark Decl. ¶¶ 6-19; Sheridan Decl. ¶¶ 60-101. In the event Yesafili were later removed from the market, Defendants' at-risk launch also would cause Regeneron to suffer loss of reputation and goodwill should Regeneron attempt to recapture the higher prices eroded by Defendants. See Clark Decl. ¶ 11; Sheridan Decl. ¶¶ 84-87. And, in the event Yesafili were later removed from the market by a subsequent injunction, Regeneron also would suffer loss of reputation and goodwill associated with being faulted for the removal of a competing product from the market.

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While Defendants will lose some prospective revenue from issuance of an injunction, those lost sales of Yesafili do not tip the balance in Defendants' favor. Defendants' lost sales would result from their decision to develop and seek to market Yesafili, a drug product the Court has determined infringes valid claims of the Product Patent. Such lost infringing sales typically are not given meaningful weight in a balance of hardships analysis. See Celsis In Vitro, Inc., 664 F.3d at 931 ("[T]he preliminary record suggests that LTC's losses were the result of its own calculated risk in selling a product with knowledge of Celsis' patent."); Acumed, 551 F.3d at 1330 (finding no abuse of discretion where a district court did not consider [the accused infringer's] expenses in designing and marketing the [accused product], since those expenses related to an infringing product"); Qualcomm, 543 F.3d at 704 (agreeing that an accused infringer "should not be permitted to prevail on a theory that successful exploitation of infringing technology shields a party from injunctive relief" (internal quotation marks omitted)); Sanofi-Synthelabo, 470 F.3d at 1383 (noting that the accused infringer's harms were "almost entirely preventable" and "the result of its own calculated risk" (internal quotation marks omitted)); Windsurfing Int'l v. AMF, 782 F.2d 995, 1003 n.12 (Fed. Cir. 1986) ("One who elects to build a business on

a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected."). And, even were Defendants' lost sales given full weight here, the Court would find they do not outweigh the above-described irreparable harms that Regeneron would incur in the absence of an injunction.

The Court's conclusion on this factor is further supported by the fact that Defendants have not yet launched Yesafili. An injunction therefore will not force Defendants to withdraw their product from the market and face the potential consequences and harms that may flow from such withdrawal. Instead, an injunction simply will maintain the status quo, a possibility regardless given the Court's infringement findings. See Impax Lab'ys, Inc. v. Aventis Pharms., Inc., 235 F. Supp. 2d 390, 396 (D. Del. 2002) ("[G]ranting the Motion for Preliminary Injunction will cause Impax only minimal hardship since doing so will leave Impax in the same position as it was in before the injunction was granted, i.e., excluded from the riluzole market."). The harm from a patentee's loss of the value of its patent is more substantial than the harm from an accused infringer's inability to enter the market earlier. See Glaxo Grp. Ltd. v. Apotex, Inc., 64 F. App'x 751, 756 (Fed. Cir. 2003) ("[W]ithout the preliminary injunction, Glaxo would

lose the value of its patent while Apotex would only lose the ability to go on to the market and begin earning profits earlier."). Thus, Regeneron's hardship absent an injunction outweighs Defendants' hardship if an injunction delays their early entry into the aflibercept via vial market.

The Court is not persuaded by Defendants' argument that "Regeneron secured over 12 years of regulatory exclusivity" and has "planned for" biosimilar sales. Opp. 21. Whether Regeneron already has received a period of **regulatory** exclusivity is irrelevant — the issue at hand is Regeneron's **patent** exclusivity. Likewise, that Regeneron has taken steps to prepare for potential biosimilar entry does not mean it should be forced to incur the harms associated with Defendants' infringing sales. See Novartis Pharms. Corp. v. Accord Healthcare Inc., 2019 WL 2588450, *5 (D. Del. June 24, 2019) ("[T]he fact that Novartis is preparing, as best as it can, to deal with legitimate generic competition when it arrives does not mean that Novartis should be confronted with premature [(likely infringing)] generic competition."). Finally, the Court gives no weight to Defendants' references to the currently unproven and disputed allegations of misconduct with respect to certain Eylea sales, Opp. 20-21, or to Defendants' contention that denial of an injunction would dampen industry

incentives to develop biosimilars, id. at 22, as this factor considers the balance of hardships only "between a plaintiff and a defendant," Acumed, 551 F.3d at 1330 ("[T]he balance considered is only between a plaintiff and a defendant, and thus the effect on customers and patients alleged by Stryker is irrelevant under this prong of the injunction test."). The Court further finds that even if the above arguments were properly considered in a balance of hardships analysis, they would not tip the scales here and outweigh the irreparable harms Regeneron would endure in the absence of an injunction.

C. Public Interest

The final factor in the injunctive relief analysis requires the Court to consider the impact of an injunction on the public interest. See Hybritech Inc. v. Abbott Lab'ys, 849 F.2d 1446, 1458 (Fed. Cir. 1988). There is a well-recognized "public interest in protecting rights secured by valid patents." Id.; see also, e.g., Sanofi-Synthelabo, 470 F.3d at 1383-84 (Fed. Cir. 2006); Patlex Corp. v. Mossinghoff, 758 F.2d 594, 599 (Fed. Cir. 1985). This factor "nearly always weighs in favor of protecting property rights in the absence of countervailing factors, especially when the patentee practices his inventions." Apple Inc. v. Samsung Elecs. Co., 809 F.3d 633, 647 (Fed. Cir. 2015).

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Regeneron contends the public interest factor favors entry of an injunction because the public benefits from innovation in the pharmaceutical industry and that such innovation is fostered by intellectual property rights. ECF No. 708-2 at 14-16. Regeneron points out that it has invested billions to discover and develop its own medicines and argues that this work is made possible by Regeneron's intellectual property and the sales of its patent-protected products, including Eylea and Eylea HD. Id. at 14; Clark Decl. ¶ 19.

For their part, Defendants contend this factor counsels against an injunction because the public has an interest in access to lower-cost aflibercept products. Opp. 22. Defendants also advance a pair of "equity" arguments, suggesting that (i) "equity counsels against issuance of an injunction based on patent claims that were drafted after Defendants developed their Yesafili formulation," id. at 14, and (ii) because "Regeneron stipulated it would not seek an injunction for unasserted Complaint patents, which include U.S. Patent No. 11,066,458 (''458 patent') . . . it can hardly complain if no injunction issues for the similarly styled '865 patent claims," id. at 25.

The Court finds the public interest factor favors entry of an injunction. Intellectual property rights promote innovation

across a number of fields, including pharmaceuticals. The Court finds there exists a public interest in protecting such rights and encouraging this innovation. See Sanofi-Synthelabo, 470 F.3d at 1383-84; Hybritech, 849 F.2d at 1458; Patlex Corp., 758 F.2d at 599. The Court has found Defendants' sales of Yesafili would infringe valid claims of the Product Patent. The public has an interest in safeguarding these patent rights.

The Court finds the public interest in access to lower-cost aflibercept products is outweighed by the compelling public interest in fostering pharmaceutical innovation. In reaching this conclusion, the Court finds itself in company with most courts that have considered this issue, including the Federal Circuit. See, e.g., Hybritech, 849 F.2d at 1458; Douglas Dynamics, 717 F.3d at 1346 ("[T]he public has a greater interest in acquiring new technology through the protections provided by the Patent Act than it has in buying 'cheaper knock-offs.'"). The Court is not persuaded by the authority Defendants rely upon to argue the public's interest in access to less expensive medicines outweighs its interest in safeguarding patent rights and promoting innovation. Genentech, Inc. v. Immunex R.I. Corp., 395 F. Supp. 3d 357, 366 n.6 (D. Del. 2019); Biogen, 2023 WL 7130655, at *4. Defendants' cited cases address this factor only in dicta.

Further, both Genentech and Biogen ultimately cite to and rely upon the Federal Circuit's decision in Hybritech. Hybritech, however, affirmed the grant of an injunction. Id. at 1458. Indeed, the district court in Hybritech recognized that the public interest in guarding patent rights "is embodied in the Constitution and our patent laws." Hybritech, Inc. v. Abbott Lab'ys, 1987 WL 123997, at *21 (C.D. Cal. July 14, 1987). While the Federal Circuit did note that "the focus of the district court's public interest analysis should be whether there exists some critical public interest that would be injured by the grant of preliminary relief," Hybritech, 849 F.2d at 1458, the district court was able to protect such interests by tailoring its injunction to ensure (1) continuity of care for patients already being monitored with certain of the accused products and (2) that "the public will [not] have to switch to an alternative technology that is presumably less effective," Hybritech, 1987 WL 123997, at *21. No analogous public interests are at issue here — Yesafili is not yet for sale, so no continuity of care concerns are presented, and there has been no suggestion that Regeneron's own aflibercept via vial product is not at least an equally effective treatment that will be available to patients in the absence of Yesafili.

Finally, the Court gives no weight to Defendants' pair of "equity" arguments. With respect to Defendants' suggestion that "equity counsels against issuance of an injunction based on patent claims that were drafted after Defendants developed their Yesafili formulation," Opp. 24, the Court notes that Defendants have offered no authority for the proposition that Regeneron may not enforce the Product Patent because it obtained those claims after the development of Yesafili had begun.[6] Even if such "equity" arguments were properly considered in a public interest analysis, the Court does not perceive any unfairness in Regeneron's enforcing these claims against the Defendants, which had access to the publicly available application that disclosed the claimed inventions for more than fifteen years, before they even began the

[6] Defendants do not contend the doctrine of prosecution laches applies here. See Cancer Rsch. Tech. Ltd. v. Barr Lab'ys, 625 F.3d 724, 728 (Fed. Cir. 2010) (explaining that "[p]rosecution laches is an equitable defense to a charge of patent infringement" that "may render a patent unenforceable when it has issued only after an unreasonable and unexplained delay in prosecution that constitutes an egregious misuse of the statutory patent system under the totality of the circumstances" (quotations omitted)). And, even if Defendants had plead this affirmative defense, which they did not, see ECF No. 505-4; see also Fed. R. Civ. P. 8(c) ("In responding to a pleading, a party must affirmatively state any avoidance or affirmative defense, including . . . laches . . . ."), they have not demonstrated the necessary "unreasonable and unexplained delay" or "egregious misuse."

development of Yesafili. Nor does the timing of the Product Patent's issuance create any unfairness with respect to its patent term, which is tied not to the date of issue but rather to the date on which the original non-provisional application was filed in 2007. The Court is likewise unpersuaded by Defendants' argument that because "Regeneron stipulated it would not seek an injunction for unasserted Complaint patents, which include U.S. Patent No. 11,066,458 (''458 patent') . . . it can hardly complain if no injunction issues for the similarly styled '865 patent claims." Opp. 25. Regeneron stipulated it would not seek an injunction on the '458 Patent and certain other patents specifically because it was seeking an expedited schedule and the opportunity to pursue injunctive relief on the Product Patent. ECF No. 78 at 1-2; ECF No. 90 at 10-12, 24.

Thus, for these reasons, the Court finds this final factor likewise counsels in favor of granting the requested injunctive relief. One additional basis, however, requires specific mention as the Court does not consider it a valid ground in its public interest analysis.

Regeneron urges that the public interest is served by denying Biocon access to the market as [redacted]

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[redacted]

Defendants also argue that the Court need not credit the arguments made regarding [redacted] According to Defendants, the FDA review and approval process involves the review of manufacturing documentation, in-person inspection of manufacturing facilities, and confirmation of compliance with Good Manufacturing Practices. (Id.; ECF No. 722-17, Abraham Decl. ¶¶ 20-22; see also, e.g., FDA Approves First Interchangeable Biosimilars to Eylea (FDA noting that "[a]ll

biological products are approved only after they meet FDA's rigorous approval standards.")).[7]

Regarding Regeneron's argument that the Court must consider [redacted].

In addition, the Court rejects this consideration in its public interest factor assessment given its role. Courts do not — or, at least, should not — declare what the law is or make

[7] https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-first-interchangeable-biosimilars-eylea-treat-macular-degeneration-and-other-eye.

[8] [redacted]

policy. That responsibility is reserved unto the other branches of government. Here, Regeneron urges the Court to assume the remaining steps of the legislative process (bicameral passage and Presidential signature or overridden veto) and instill the force of law into introduced[9] and pending legislation. This Court declines that invitation.

* * *

The Court recognizes the apparent tension between traditional patent law concepts and the BPCIA, particularly as it pertains to the eBay public interest factor. Of course, "the public has a well-recognized interest in protecting patent rights and fostering innovation," Apple, 809 F. 3d at 647, Congress also has enacted significant legislation, the BPCIA, that is designed to foster competition and make alternative and lower-cost therapeutics available to patients, and Courts have expressly found in the BPCIA biosimilar context that "[f]or pharmaceutical drugs that prolong and save lives, there is a critical public interest in affordable access to those drugs," Genentech, Inc. v. Immunex Rhode Island Corp., 395 F. Supp. 3d 357, 366 n.6 (D. Del. 2019), aff'd, 964

[9] Respectfully, and not specific to [redacted], the only constraint on introducing legislation, even at the federal level, is the sponsor's imagination, which only highlights the need for courts to refrain from fast-forwarding past the necessary steps set forth in the Constitution.

F.3d 1109 (Fed. Cir. 2020); see also Janssen Biotech, Inc. v. Celltrion Healthcare Co., 210 F. Supp. 3d 244, 252 (D. Mass. 2016) (recognizing a strong public interest in "[a] less expensive biosimilar alternative to compete fairly with [the reference product]"). The parties repeatedly made clear – during the contentious, protracted dispute over the proper schedule governing discovery and trial - this matter presented one of the first, if not the first, BPCIA case to proceed on a trial trajectory. None of the cases that Regeneron provides to the Court are directed to biosimilar litigation, and indeed they mostly pre-date the BPCIA, and in some cases, pre-date even eBay.

Nonetheless, after considering the applicable authority, even if not squarely within BPCIA's umbrella, the Court ultimately concludes that the public interest factor also weighs in favor of permanent injunctive relief here.

V. CONCLUSION

After a nine-day bench trial, the Court held that Defendants infringed claims 4, 7, 9, 11, 14, 15, 16, and 17 of the '865 Patent and that Defendants did not demonstrate by clear and convincing evidence that claims 4, 7, 9, 11, 14, 15, 16, and 17 of the '865 Patent are anticipated or obvious in light of the prior art or invalid under 35 U.S.C. § 112 for lack of written description,

lack of enablement, or indefiniteness. Upon consideration of Plaintiff's Motion for Permanent Injunction, accompanying Memorandum in Support, exhibits attached thereto, and all the evidence presented before this Court, including at trial, for the reasons set forth below, it is **ORDERED THAT:**

Plaintiff's Motion for a Permanent Injunction is **GRANTED.**

Pursuant to Federal Rule of Civil Procedure 65(d)(1), and for the reasons provided herein, the Court makes the following findings and conclusions based upon the record developed in connection with Regeneron's motion.

1. Defendants sought FDA approval via their Biologics License Application No. 761274 to market a biosimilar version of Regeneron's drug Eylea. Defendants' product that is the subject of this BLA is also known as "Yesafili."

2. After a nine-day bench trial, the Court determined that Defendants would infringe claims 4, 7, 9, 11, 14, 15, 16, and 17 of the '865 Patent by making, using, selling, or offering for sale Yesafili, or importing Yesafili into the United States.

3. After the same nine-day bench trial, the Court determined that that Defendants did not demonstrate by clear and convincing evidence that claims 4, 7, 9, 11, 14, 15, 16, and 17 of the '865 Patent are anticipated or obvious in light of the prior

art or invalid under 35 U.S.C. § 112 for lack of written description, lack of enablement, or indefiniteness.

4. Regeneron has demonstrated that any manufacture, importation, or commercialization of Yesafili prior to the expiry of the '865 patent will cause it irreparable harm.

5. Regeneron has demonstrated that the balance of hardships favors Regeneron, not Defendants.

6. Regeneron has demonstrated that the public interest favors granting the permanent injunction in order to protect intellectual property rights and because the public is already able to receive aflibercept via vial in the form of Eylea.

A. Scope of Injunction and Meet-and-Confer Requirement

The Court is mindful that there are complexities associated with [redacted] — markets which are beyond the territorial reach of U.S. patent laws. Microsoft Corp. v. AT&T Corp., 550 U.S. 437, 454–55 (2007) ("The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law."). In order to ensure that the injunction entered by this Court does not [redacted], **the Court hereby orders the parties**

to meet and confer regarding the conditions and scope of the injunction and jointly submit to the Court a proposed form of injunction order within five (5) business days of entry of this order. The Court further finds that because the only harm that Regeneron presented in the record of these injunction proceedings is directed to commercial marketing within the U.S., the proposed form of injunction should likewise be restricted to prohibiting the commercial sale to customers in the U.S. of the Biocon BLA No. 761274 product that the FDA approved May 20, 2024.

B. Meet-and-Confer on Public Order

The Court is filing this Order under seal, as the Court understands that there is information herein that the parties have designated Confidential or Outside Counsel Eyes Only under the Protective Order. The Court expects the parties to confer on preparing and submitting a public version containing appropriate redactions to protect each party's confidential information. The parties shall meet and confer to discuss which portions of this Order can be unsealed. **They shall submit a joint proposed redacted version for the Court's review within seven (7) days of the entry of this Order.**

C. Order Pursuant To Fed. R. Civ. P. 54(B)

At a recent hearing before the Court, both Regeneron and Mylan/Biocon stated their interest in having the Court further certify its Trial Decision and this order pursuant to Federal Rule of Civil Procedure 54(b) for entry of final judgment in accordance with the issues previously tried, including the Court's Findings of Fact and Conclusions of Law (ECF No. 664) pertaining to the patents asserted, namely the '572 Patent; the '601 Patent; and the '865 patent.[10] (ECF No. 778, May 17, 2024 Hearing Tr. at 14-15 (Regeneron), 13-14 (Mylan/Biocon)). Having considered the matter, and in view of the agreement by the parties, and in view of the facts set forth below, this Court agrees that entry of judgment pursuant to Rule 54(b) is appropriate, and as such this Order further directs entry of final judgment as to Counts 12, 17, and 21 of Regeneron's Complaint pursuant to Federal Rule of Civil Procedure 54(b). (ECF No. 1 (Complaint)).

Federal Rule of Civil Procedure 54(b) provides, in relevant part, "[w]hen an action presents more than one claim for relief,

[10] The Court notes the parties' respective interest in the swift adjudication of this matter has vacillated during this phase's pendency. Regardless, for the reasons set forth hereinafter, the Court finds it appropriate to certify the judgment(s) rendered to date under Rule 54(b) so the parties may take their respective appeals.

whether as a claim, counterclaim, crossclaim, or third-party claim, or when multiple parties are involved, the court may direct entry of final judgment as to one or more, but fewer than all, claims or parties only if the court expressly determines that there is no just reason for delay." Fed. R. Civ. P. 54(b).

The Supreme Court has established a two-part test for determining when Rule 54(b) certification is appropriate. First, the district court must determine that its decision is a "final" judgment as to the relevant claim. Curtiss-Wright Corp. v. Gen. Elec. Co., 446 U.S. 1, 7 (1980). Second, the district court must expressly determine that there is "no just reason for delay." Id. at 8. For the reasons explained below, both requirements are satisfied here.

The Court hereby states that for purposes of Rule 54(b), the Court has rendered a "final" judgment on the '572, '601, and '865 patents in its Trial Decision, because it has ruled on Regeneron's infringement claims, Defendants' dispositive defenses, and on Regeneron's request for injunctive relief (which Regeneron limited to the '865 patent). And, as set forth below, there is also no just reason for delay. Thus, the two-part test is satisfied here.

Uncontroverted facts in support of Rule 54(b) certification include:

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1. In June 2023, the Court presided over a two-week trial on Regeneron's claims of infringement of claims 4, 7, 9, 11, and 14-17 of the '865 patent, claims 6 and 25 of Regeneron's '572 Patent; and claims 11 and 19 of Regeneron's '601 Patent; as well as Defendants' counterclaims of invalidity of those patent claims.
2. On December 27, 2023, the Court entered findings of fact and conclusions of law holding that claims 4, 7, 9, 11, and 14-17 of the '865 patent asserted by Regeneron at trial were infringed and not invalid; that claims 6 and 25 of the '572 patent were infringed and invalid; and that claims 11 and 19 of the '601 patent were infringed and invalid.
3. With the present Order, the Court is also issuing judgment on Regeneron's request for permanent injunction, which resolves the sole remedy request by Regeneron for the '865 patent.
4. No claims or counterclaims remain with respect to the '865 patent, the '572 patent, or the '601 patent.
5. On January 26, 2024, both Regeneron and Mylan/Biocon filed protective Notices of Appeal to the Court of Appeals for the Federal Circuit. The Federal Circuit

dismissed those appeals for lack of a final judgment on April 12, 2024.

6. On May 17, 2024, both parties represented to this Court that they wished the Court to enter a final judgment pursuant to Federal Rule of Civil Procedure 54(b), to allow the parties to proceed to an appeal of the Court's judgments on the '865, '572, and '601 patents.

7. There is no just reason to delay the Court's judgment concerning these patents. The Court's conclusive findings in the Trial Decision on the '865, '572, and '601 patents are separable from and not intertwined with Regeneron's remaining claims and Defendants' related counterclaims, which involve alleged infringement and invalidity defenses of other patents.

8. There is no risk that further proceedings in the case between Regeneron and Mylan/Biocon will moot the need for Federal Circuit review of the Court's findings of fact and conclusions of law in the Trial Decision, or in the present Injunction Order.

9. An expedited Federal Circuit review will also serve principles of judicial efficiency, as separate defendants before this Court in multidistrict litigation

are also involved in litigation with Regeneron involving these same patents.

10. The Court's merits decisions with respect to the '572, '601, and '865 patents, and Defendants' BLA product, are ripe for appellate review now, and will not be rendered moot by any proceedings currently pending before this Court involving Regeneron and Defendants for that accused product.

11. The equities also weigh in favor of appeal of the Court's findings of fact and conclusions of law in the Trial Decision, instead of delaying review pending the adjudication of the remaining unrelated claims. As noted above, both parties previously filed Notices of Appeal of the Court's judgment, and both parties have represented to this Court their interest in having issues addressed and resolved promptly on appeal.

12. There further is a public interest in having these claims under the BPCIA resolved, because the outcome at the Federal Circuit may ultimately facilitate Defendants' product reaching the market earlier without infringement liability risk.

i. The Court's Decision as to the '572, '601, and '865 Patents Is Now Final

"The Supreme Court has stated that a district court's judgment is final where it 'ends the litigation on the merits and leaves nothing for the court to do but execute the judgment.'" W.L. Gore & Assocs., Inc. v. Int'l Med. Prosthetics Rsch. Assocs., Inc., 975 F.2d 858, 863 (Fed. Cir. 1992) (quoting Catlin v. United States, 324 U.S. 229, 233 (1945)).

This Court has rendered a "final" judgment on the '865 patent because it has ruled that the claims of the '865 patent asserted by Regeneron at trial were infringed and not invalid, and with this Order is adjudicating Regeneron's request for injunctive relief. See id. ("Because the infringement claim and several dispositive defenses were ruled upon, the district court's judgment was final."); Creative Compounds, LLC v. Starmark Lab'ys, 2009 WL 5171738, at *1 (Fed. Cir. Dec. 30, 2009).

The Court has rendered a "final" judgment on the '572 and '601 patents because it has ruled that the claims of those patents asserted by Regeneron at trial were infringed but invalid, and in view of that ruling, Regeneron is not permitted any further remedy.

Thus, the Court's holdings as to the validity and infringement of the asserted claims of the '865 patent, and invalidity and infringement of the asserted claims of the '572 and '601 patents,

are final and appealable. See PODS, Inc. v. Porta Stor, Inc., 484 F.3d 1359, 1365 (Fed. Cir. 2007).

ii. There Is No Just Reason for Delay of Entry of Final Judgment

"[I]n deciding whether there are no just reasons to delay the appeal of individual final judgments in setting such as this, a district court must take into account . . . the equities involved." Curtiss-Wright, 446 U.S. at 8. Courts have determined that equity favors entry of final judgment under Rule 54(b) when appeal of such a judgment could bring the generic version of a pharmaceutical product to market faster than would occur absent such an entry. See Sun Pharms. Indus. Ltd. v. Eli Lilly & Co., 2009 WL 3497797, at *2 (E.D. Mich. Oct. 29, 2009).

Regeneron acknowledges that, "[a]s of May 18, 2024 . . . the only impediments to Defendants' planned launch of Yesafili are Regeneron's patent rights," specifically the '865 patent. (ECF No. 708-3 at 2). Defendants wish to appeal the Court's adverse infringement and validity judgments on the '865 patent. Regeneron wishes to appeal the Court's adverse invalidity judgments against it on the '572 and '601 patents. (ECF No. 778, May 17, 2024 Hearing Tr. at 14-15 (Regeneron), 13-14 (Mylan/Biocon)).

Both parties also concede that prompt appeal of the Court's holdings as to the '865 patent would, if the Defendants prevail on

the merits, allow the Defendants to bring Yesafili to market shortly after that date. (ECF No. 708-3 at 2; see also ECF No. 779, May 17, 2024 Hearing Tr. at 13-14).

Defendants have expressed that expedited entry of Yesafili to the market has the potential to lower costs for consumers, which expands access to a wider patient population that would benefit from those lower costs in battling their (potentially sight-threatening) ophthalmic disorders. (ECF No. 722-1, Defendants' Opposition Brief at 2-3; ECF No. 774, Defendants' TRO Brief at 15; ECF No. 691 at 10). Defendants have further emphasized the critical importance of being first to market, and not losing the advantage they have obtained against their other competitors by litigating early under the BPCIA. (ECF No. 722-1, Defendants' Opposition Brief at 21; ECF No. 691 at 6).

Regeneron wishes to appeal to try to preserve the patents that the Court has held invalid, to forestall further market entry, or receive damages if the Court's invalidity findings warrant reversal. (ECF No. 680-1).

Moreover, regardless of the Federal Circuit's decision as to the validity or infringement of the '865, '572, and '601 patent claims, resolution of an appeal serves the public interest by "resolving questions of patent validity." Cardinal Chem. Co. v.

Morton Int'l, Inc., 508 U.S. 83, 100 (1993). This is especially important here, where Regeneron is presently asserting claims from these same patents against a series of separate Defendants, which cases were recently consolidated before this Court by the Judicial Panel on Multidistrict Litigation. (MDL ECF No. 1 (24-md-3103-TSK)). The Court encourages both parties to cooperate to expedite their respective appeals, as this will also contribute to judicial efficiency and conservation of resources.

"[I]n deciding whether there are no just reasons to delay," the Court also should "consider such factors as whether the claims under review were separable from the others remaining to be adjudicated and whether the nature of the claims already determined was such that no appellate court would have to decide the same issues more than once even if there were subsequent appeals." Curtis-Wright, 446 U.S. at 8. For purposes of assessing finality under Rule 54(b), infringement claims and invalidity counterclaims of a patent are separate from infringement claims and invalidity counterclaims of other patents assigned to the same entity even if directed to the same subject matter. See Sun Pharms., 2009 WL 3497797, at *2, aff'd, 611 F.3d 1381 (Fed. Cir. 2010).

Following Sun, the Court's holdings — namely that the asserted claims of the '865 patent asserted by Regeneron at trial

were both (1) not invalid and (2) infringed by the Defendants' BLA, and also that the asserted claims of the '572 and '601 patents asserted by Regeneron at trial were both (1) invalid and (2) infringed by the Defendants' BLA — are unrelated to whether any of the claims of the other patents Regeneron has asserted against the Defendants are invalid or infringed.

Similarly, the issues that the Federal Circuit would rule upon remain the same: whether the '865 patent is not invalid and infringed by the Defendants' BLA, and whether the '572 and '601 patents are invalid and infringed. (ECF No. 1, Seventeenth Cause of Action, ¶¶ 183-92; ECF No. 435, Count 17, ¶¶ 153-59 (the '865 patent), Twenty-First Cause of Action ¶¶ 223-32 (the '572 patent), Twelfth Cause of Action, ¶¶ 133-42 (the '601 patent)).

Thus, the Court hereby **ORDERS** entry of final judgment pursuant to Federal Rule of Civil Procedure 54(b) for Counts 12, 17, and 21.

It is so **ORDERED**.

The Clerk is **DIRECTED** to transmit copies of this Order only to counsel for Regeneron, Mylan, and Biocon.

DATED: June 11, 2024

Tom S Kleeh

THOMAS S. KLEEH, CHIEF JUDGE
NORTHERN DISTRICT OF WEST VIRGINIA